

readmission reason from a family member/caregiver perspective.

**Conclusion:** While our 30 day readmission rate has decreased from 34.6 in 2009 to current rate of 23.5 (See Figure), we still have work to do. The initial reduction cannot be attributed to any particular effort(s) and we will continue to be diligent and innovative in this endeavor. Some readmissions are not preventable and fevers are a big barrier. In the near future we hope to create a working group with other institutions, focus on the patients who are readmitted frequently, and develop criteria to define what a true preventable readmission is.

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### Building a Quality Plan for a Blood and Marrow Transplant Program: Quality Framework and Indicator Development

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**Introduction:** Quality of care is a priority among patients, providers, and accreditors in blood and marrow transplantation (BMT), and has resulted in the need to develop quality management systems. BMT programs can apply quality frameworks such as the Model for Improvement, which guide programs to set quality goals, and to develop quality measurement and reporting strategies to ensure progress toward those goals. We report on the systematic, end-user-informed development of a set of quality indicators, to be monitored and reported on in the context of a quality framework at the Princess Margaret Cancer Centre BMT program.

**Methods:** This involved three phases: 1) Evidence Review (database and grey literature search for quality indicators used in BMT); 2) Modified Delphi process, in which identified indicator concepts were discussed to generate a list of broad clinical categories, then prioritized via a staff survey; and 3) investigation of the published literature for data standards for these indicators.

**Results:** Evidence review generated 214 indicators, which were categorized as Clinical (n=139), Management-level (n=40), or Hospital-wide (n=35). Only the Clinical indicators were deemed meaningful for staff prioritization. By merging like concepts, the 139 indicators were reduced to 22 for inclusion in the prioritization exercise. Prioritization was achieved through an online survey sent to 152 clinical BMT staff. Respondents ranked indicators based on their perceived clinical value as quality measures. Respondents ranked "Survival" and "Treatment-related mortality" most frequently in their top 3 choices. However, a low survey response rate (35 of 152, or 23%) suggested a lack of staff awareness of quality measurement, and a need to coordinate staff education and creation of a quality improvement culture to ensure success of such initiatives in the future. Next, Management-level indicators were pared down through discussion and consensus, generating 12 indicators to be developed for future reporting. The Hospital-wide indicators, which were non-BMT-specific but could be adapted for use in BMT quality measurement, were mapped to corresponding Management-level and Clinical indicators. Their existing measurement structures may be useful in developing measurement strategies for our BMT-specific quality indicators. Finally, working

toward eventual implementation, all indicators were assessed for any data standards mentioned in the literature. Our findings revealed a paucity of published data standards for BMT quality indicators, highlighting a need for more research in this field.

**Conclusions:** Quality indicator development in BMT can be undertaken systematically, but requires a concerted effort from staff engagement to informatics infrastructure. Currently, this area is challenged by a lack of published development standards and implementation studies.

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### Is G-CSF Still Needed Post-Transplant to Promote Engraftment in the Present Era? a Multi-Disciplinary Project to Evaluate Patient Safety vs. Cost Savings

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**Background:** The use of granulocyte colony stimulating factor (G-CSF) to promote engraftment after hematopoietic cell transplantation (HCT) remains controversial. Randomized controlled trials that showed a shorter duration of neutropenia after G-CSF in autologous (auto) HCT recipients were performed in an era when present supportive care resources were not available. The use of G-CSF after allogeneic (allo) HCT is not established by randomized trials and there is a concern that it may be associated with an increased risk of graft-versus-host disease. G-CSF is a costly drug and excluding its routine use may translate into significant cost savings for a transplant program. All inpatients transplanted routinely receive G-CSF 480 mcg/day starting day +5. We conducted a pilot study to evaluate if G-CSF post-HCT could be safely omitted after autologous and allogeneic HCT.

**Methods:** 2013 data was used as benchmarks for neutrophil engraftment and hospital length of stay (LOS), calculated from day 0. Three separate pilots were conducted for auto HCT, myeloablative (MAC) allo and reduced-intensity (RIC) allo HCT recipients. Eligibility criteria included sufficient cell dose for the product to be infused (PBSC  $\geq 5.0 \times 10^6$  CD34+ cells/kg for autos,  $\geq 2.0 \times 10^6$ /kg for allos or BM  $\geq 2.0 \times 10^8$  TNC/kg). G-CSF was not administered prophylactically, but could be given in clinical scenarios such as prolonged febrile

**Table**

G. CSF Pilot Interim Analysis		
	No G. CSF Median (Days)	G CSF Control (Days)
Autologous (7 Cases, 10 Controls)		
LOS	15	12
Neutrophil Engraftment	12	10
Allogeneic MAC (BM & PBPC) (9 Cases, 9 Controls)		
LOS	22	17
Neutrophil Engraftment	22	12
Allogeneic RIC (PBPC) (10 Cases, 10 Controls)		
LOS	19	17
Neutrophil Engraftment	14	13

neutropenia or engraftment not occurring by day +21. Accrual target was 20 patients for each group with a planned interim analysis after ~10 patients. For each pilot patient, a control was randomly selected from 2013; controls were matched by age, graft source, diagnosis and cell dose. Implementation of the pilot was the effort of a multi-disciplinary team including physicians, mid-level providers, nurses, clinical pharmacists, data and quality assurance personnel.

**Findings:** For the auto and allo MAC groups, interim analysis revealed that omission of G-CSF led to longer LOS and longer time to neutrophil engraftment (see Table). The interim analysis of the allo RIC group appears to be comparable for the length of stay and neutrophil engraftment.

**Discussion:** Any cost savings of not using G-CSF are likely to be offset by the longer duration of post-transplant hospitalization and possible increased risks due to longer periods of neutropenia. Based on our findings, the pilot has been discontinued for auto and allo MAC transplants, where we will continue to use G-CSF starting on Day +5 to promote engraftment. This pilot will accrue the planned 20 patients for allogeneic RIC patients before a final analysis is performed.

## PHARMACY

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#### Folinic Acid Rescue after Methotrexate Graft Versus Host Disease Prophylaxis to Reduce Mucositis and Improve the Probability of Day +11 Methotrexate Administration - Role of the Hematopoietic Cell Transplant Pharmacist in Development of Program Guidelines

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**Background:** Methotrexate (MTX) is routinely utilized for prophylaxis of graft versus host disease (GVHD). MTX may contribute to mucositis and delayed engraftment. Severe mucositis results in MTX dose reduction, holding day +6 and/or day +11, addition of folinic acid (FA), or the use of dexamethasone. Delivery of day +11 MTX has been reported to be important in reducing the risk of aGVHD. FA administration after MTX doses has been shown to reduce MTX toxicity. In an effort to reduce the incidence of mucositis to improve the likelihood of administering day +11 MTX and to provide a consistent treatment guideline, the Hematopoietic Cell Transplant (HCT) program director enlisted the help of the HCT pharmacist to review the data and recommend guidelines.

**Methods:** A review of the literature for post-MTX FA use was performed and presented at an HCT program education session. FA dosing, time of initiation post MTX, schedule and number of doses were discussed. The HCT providers agreed to follow the HCT pharmacist recommendation of FA 10mg/m<sup>2</sup> IV every 6 hours x 3 doses starting 12 hours after each MTX dose (day +1, +3, +6 and +11) with myeloablative (MA) conditioning regimens. All patients received tacrolimus. Data was retrospectively collected in 2013 after the FA guideline was adopted and compared to consecutive patients receiving MA regimens from a control group in 2012. The primary endpoint was administration of full dose day +11 MTX. Sec-

ondary endpoints were rates of aGVHD, cGVHD, total parenteral nutrition (TPN) use, patient controlled analgesia (PCA) use, transplant-related mortality (TRM), relapse and overall survival (OS).

**Results:** The FA group consisted of 27 patients while there were 31 in the control. Patients in the FA group were more likely to receive full dose day +11 MTX as compared to control, 85.2% vs 48.4% ( $p=0.0025$ ) and were less likely to require PCA, 63% vs. 87.1% ( $p=0.03$ ). There was no significant difference in rates of TPN use (48.2% vs. 58.1%), grade II-IV aGVHD at day 100 (50.4% vs. 30.5%), cGVHD (19.9% vs. 27.7%), cumulative incidence of relapse (10.8% vs. 8.6%), TRM at 1 year (13.1% vs. 19.5%) and OS at 1 year (77.9% vs. 75.9%) for the FA group and control, with a median follow-up of 465 days and 670 days, respectively.

**Discussion:** Patients experienced less mucositis and were more likely to receive full dose day +11 MTX after implementation of the FA guideline. This was also supported by a statistically significant decrease in PCA use. Other endpoints trended in a favorable direction, but did not reach statistical significance. The development and utilization of the program guideline improved consistency of care, improved staff satisfaction and decreased patient discomfort. HCT pharmacists play an important role in the review of literature and development of program guidelines.

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#### Evaluation of the Impact of Anti-Thymocyte Globulin (ATG) on Post-Hematopoietic Cell Transplant (HCT) Outcomes in Patients Undergoing Allogeneic HCT

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**Background:** Anti-thymocyte globulin (ATG) is often incorporated into allogeneic stem cell transplant (alloHCT) conditioning regimens to prevent graft-versus-host disease (GVHD). Literature regarding the effect of ATG on outcomes is mixed; some data suggests an improvement in GVHD control with ATG use, but other data shows a reduction in overall survival, particularly in the reduced intensity setting. This study evaluates the impact of ATG on infection, GVHD, relapse, and mortality rates in adult alloHCT patients.

**Methods:** A retrospective review of 250 adult alloHCT patients at our institution (125 unrelated/mismatched donor recipients received ATG, 125 matched related donors did not) between 2006 and 2013 was performed. Charts were reviewed for ATG use, demographics, infections (bacterial, viral, fungal), infection source, GVHD, day-180 relapse, and day-180 mortality. The primary endpoint was infection rate; secondary endpoints included mortality and GVHD.

**Results:** Factors with significant impact on infection incidence were conditioning type (Myeloablative (MAC) > Reduced Intensity (RIC),  $p=0.0105$ ), age ( $p=0.0245$ ), and use of ATG ( $p=0.0185$ ). MAC was associated with greater